REMARKS

These remarks are directed to the Office Action dated November 2, 2010. Citations to paragraphs of the specification refer to the published application, U.S. Publication No. 2006/0239884.

Claims 1-7, 9-15, 17 and 19-22 are pending. Claims 8, 16 and 18 were previously canceled.

Claims 1, 10 and 11 stand rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement.

Claims 1-7, 10 and 11 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention.

Claims 1-3, 5 , 7 and 9 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Itoi, U.S. Patent No. 6,159,437 ("Itoi").

Claims 1 and 2 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Roeder et al., U.S. Publication No. 2003/0031698 ("Roeder").

Claims 1-3, 5 , 7 and 9 stand rejected under 35 U.S.C. § 103(a) as being unpatentable as obvious over Itoi, U.S. Patent No. 6,159,437 ("Itoi").

Claims 1-4, 6, 9-15, 17 and 19-22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable as obvious over Roeder et al., U.S. Publication No. 2003/0031698 ("Roeder").

Claims 14 and 21 stand rejected under 35 U.S.C. § 103(a) as being unpatentable as obvious over Roeder in view of Kumta et al., U.S. Patent No. 7,247,288 ("Kumta").

Claims 1-5, 9-15, 17 and 19-22 stand rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-6 of U.S. Patent No. 7,807,724.

Claims 1-15, 17, and 19-22 are pending. Claims 1, 10 and 11 are amended to delete the term "highly" and to recite that the range of particle size in the aqueous dispersion is at least 80% between 250 nm and 600 nm. No new matter is added by these amendments. Claims 2-7 depend from claim 1, and the preambles of the dependent claims have been amended to recite that the claims refer to the "aqueous dispersion of separated calcium phosphate platelets" recited in claim 1.

Rejections Under 35 U.S.C. § 112

The amendments to the claims have addressed all of the rejections under 35 U.S.C. § 112. The term "highly" in reference to the crystallinity of the calcium phosphate particles has been deleted from claims 1, 9 and 10. The particle size range has been amended in claims 1, 9 and 10 to recite the range for the dispersion described in paragraph [0039] of the specification. Claims 2-7 have been amended by clarifying in the preamble that the claims refer to the aqueous dispersion of calcium phosphate platelets of claim 1.

With these amendments, the rejections under 35 U.S.C. § 112 are moot.

Rejection of claims 1-3, 5, 7 and 9 Under 35 U.S.C. Section 102(b) Based on Itoi

Claims 1-3, 5, and 7-9 stand rejected under Section 102(b) as anticipated by Itoi. The Office Action states that Itoi discloses a composition comprising an aqueous dispersion of separated calcium phosphate platelets that exhibit apatite structure and have dimensions of 30-300 nm by 100-1000 nm (Office Action, page 5).

To anticipate a claim under Section 102(b), a single prior art reference must disclose each and every element set forth in the claim. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987); MPEP § 2131. Itoi does not describe or disclose an aqueous dispersion of calcium phosphate platelets having the particle size distribution recited in claim 1. Itoi describes calcium phosphate slurries in water-compatible organic solvents. See Itoi Abstract; col. 3, lines 36-46; claim 1. While Itoi states that up to 50 percent by weight water may be added to the organic solvent, Itoi makes clear that the organic solvent must be the primary component to obtain the desired slurry.

The Examiner suggests that the description of a slurry in an organic solvent that contains water is an "aqueous dispersion." One skilled in the art would not view the dispersion in organic solvent described in Itoi as an aqueous dispersion merely because some water might be added to the organic solvent. An aqueous dispersion is a dispersion in water. The examples of the invention described in Table 1 of Itoi all contain ethylene glycol as the organic solvent. Figure 2 of Itoi shows

the degree of dispersion in the slurry of Example 2. Example 2 uses ethylene glycol (without water) as the organic solvent.

The only aqueous dispersions described in Itoi are the comparative examples. As shown in Figures 3-5, which show the particle size dispersion in the comparative examples of Itoi, the aqueous slurries do not have a particle size distribution meeting the limitations recited in claim 1. Accordingly, for at least these reasons, Itoi does not anticipate claims 1-3, 5, 7 and 9 as amended.

Rejection of Claims 1 and 2 Under 35 U.S.C. Section 102(b) Based on Roeder

Claims 1 and 2 stand rejected as anticipated by Roeder (US 2003/0031698). Roeder does not disclose an aqueous dispersion of calcium phosphate platelets wherein at least 80% of the platelets have a length of between 250 nm and 600 nm as recited in claim 1. Roeder does not describe aqueous dispersions of calcium phosphate platelets at all. Roeder describes anisometric calcium phosphate reinforcement particles within a thermoplastic polymer matrix or a calcium phosphate-based matrix, such as a cement, for use in orthopedic implants (Roeder, paragraphs [0010], [0027], [0029], [0030]). The matrices of Roeder are not aqueous. Moreover, the calcium reinforcement particles have a mean length of between 1 micrometer to 500 micrometers. Paragraph [0034]. This is well above the size range recited in claim 1.

The Examiner cites Paragraph [0035] of Roeder as disclosing an aqueous dispersion of calcium phosphate particles having a mean dimension of 1 to 500 nm. This is not a correct reading of this paragraph. In Paragraph [0035], Roeder states that some smaller particles may be included in the matrix. As discussed above, the matrix materials of Roeder are not aqueous, and therefore do not form aqueous dispersions. In addition, the composition described in paragraph [0035] of Roeder do snot meet the particle size range recited in claim 1 as amended. Roeder states that only some smaller particles are present and, if present, they are concentrated more heavily at the surface. Roeder does not even suggest that at least 80% of the calcium phosphate particles would be in this smaller size range.

The Examiner also cites Paragraph [0047] of Roeder, which describes production of a calcium phosphate matrix material. Roeder describes the combination of calcium or phosphate

containing particles to produce the matrix material. Roeder states that the starting materials can have a particle size in the range of 1 nm to 500 nm. Roeder does not describe an aqueous dispersion of these particles. In Paragraph [0048], Roeder describes dry mixing the powders to form the matrix materials. Roeder also describes addition of other materials after dry mixing to form a paste. Roeder does not describe an aqueous dispersion of calcium phosphate platelets at all, much less describe an aqueous dispersion having the particle size distribution recited in claim 1 as amended.

Roeder does not describe aqueous dispersions at all, much less aqueous dispersions containing particles having a size in the range recited in the claims as amended. Because Roeder does not disclose all elements of the claims, Roeder does not anticipate claims 1 or 2 as amended.

Rejection of Claims 1-3, 5, 7 and 9 Under 35 U.S.C. Section 103(a) Based on Itoi

Claims 1-3, 5, 7 and 9 stand rejected under 35 U.S.C. § 103(a) as being unpatentable as obvious over Itoi. As discussed above, Itoi describes dispersions of calcium phosphate particles in a water compatible organic solvent. One skilled in the art would not be motivated to replace the organic solvent of Itoi with water to form an aqueous dispersion. Indeed, Itoi teaches away from such a modification. Itoi states that the dispersion in an organic solvent may include water, but that if greater than 50% water is added, "the apatite slurry of the present invention cannot be obtained." Col. 3, lines 47-52. Moreover, as discussed above, the comparative examples of Itoi in which water alone is used to form the slurry do not meet the particle size limitations of the claims, as shown in Figs. 3-5. As shown in Figs. 3-5, in the aqueous slurries of the comparative examples in Itoi, the particle size is almost entirely greater than 1 μm (1000 nm). Because Itoi teaches away from making an aqueous dispersion of calcium phosphate having the particle size distribution recited in the claims as amended, the claims are not obvious in view of Itoi. Accordingly, applicant respectfully requests that this grounds for rejection be withdrawn.

Rejection of Claims 1-4, 6, 9-15 and 19-22 Under 35 U.S.C. Section 103(a) Based on Roeder

Claims 1-4, 6, 9-15, 17 and 19-22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable as obvious over Roeder. Regarding claims 1-4, 6 and 9, as discussed in detail above,

Roeder describes anisometric calcium phosphate reinforcement particles within a thermoplastic polymer matrix or a calcium phosphate-based matrix, such as a cement, for use in orthopedic implants (Roeder, paragraphs [0010], [0027], [0029], [0030]). Moreover, the calcium reinforcement particles have a mean length of between 1 micrometer to 500 micrometers. Paragraph [0034]. There is nothing in Roeder that describes or suggests an aqueous dispersion of calcium phosphate platelets having the particle size range recited in claim 1 as amended. Moreover, one skilled in the art would not be motivated to modify Roeder to arrive at an aqueous dispersion as recited in the claims.

First, Roeder describes calcium phosphate particles dispersed in a thermoplastic polymer or calcium phosphate cement matrix. The matrix is used to form a biocompatible material having biomechanical properties resembling that of bone. One skilled in the art would not be motivated to replace the matrix material with water to arrive at the aqueous dispersion recited in claim 1 as amended. Indeed, if the matrix material were removed from the composition of Roeder, it would not perform its intended function. MPEP § 2143.01(V)(proposed modification to prior art cannot render the prior art invention unsatisfactory for its intended purpose).

Moreover, the reinforcement particles described in Roeder have a length of between 1 micrometer and 500 micrometers. Paragraph [0034]. While Roeder suggests that some smaller particles may be included, Roeder does not suggest that at least 80% of the particles could be of the smaller size. Replacing at least 80% of the reinforcement particles would defeat the purpose of the material described in Roeder, as the smaller particles would not provide the desired biomechanical strength. In any event, even is smaller particles were substituted, they would be contained in the matrix material and would not form an aqueous dispersion as claimed.

Finally, the description in Roeder of the process for manufacturing a calcium phosphate cement matrix does not render the claimed aqueous dispersion obvious. First, Roeder describes dry mixing of the particles to form the matrix material. After mixing, a sodium phosphate solution may be added to form a flowable paste. Paragraph [0048]. Roeder does not describe an aqueous dispersion, and Roeder is not concerned with maintaining the calcium phosphate platelets in a dispersion. The matrix is intended to be a cement type material that hardens in place. One skilled in the art would not be motivated to modify the composition for the matrix described in Roeder to form

an aqueous dispersion, as the aqueous dispersion would not function as a cement type material. MPEP § 2143.01(V)(proposed modification to prior art cannot render the prior art invention unsatisfactory for its intended purpose).

For at least the foregoing reasons, claims 1-4, 6 and 9 are not obvious in view of Roeder, and the rejection of these claims as obvious in view of Roeder should be withdrawn.

Claims 10-15 and 19-22 recite processes for making the aqueous dispersion recited in claim 1. In the processes of independent claims 10 and 11, a solution of a calcium salt with pH adjusted to between 4 and 6 is combined with a phosphate containing solution over a period of 30 minutes to four hours to obtain a calcium to phosphate molar ratio of between 1 and 2.5. The resulting solution is heated to a temperature of between 50°C to 95°C. In the embodiment recited in claim 11, the pH of the solution is adjusted to between 8 and 9.5 following heating. The resulting aqueous calcium phosphate dispersions in both embodiments have a particle size range in which at least 80% of the particles are between 250 nm and 600 nm.

In the process described in Roeder in Example 1 at Paragraphs [0056] to [0060] for producing the calcium phosphate reinforcement particles, a solution containing a mixture of calcium and phosphate are combined at room temperature at a pH of 4. To produce the calcium phosphate particles, the resulting solution is heated to a temperature of 200°C for two hours before cooling to less than 100°C in less than 1 hour. The resulting precipitate has an average length of 19 μm (19,000 nm) or more and a width of 2.3 μm (2,300 nm) or more. The process described in Roeder does not result in an aqueous dispersion of calcium phosphate particles having the particle size recited in the claims as amended. Moreover, there is nothing in Roeder that would lead one skilled in the art to modify the process in Roeder to arrive at the claimed process to produce an aqueous dispersion of calcium phosphate platelets having the particle size distribution recited in the claims as amended. The process of Roeder requires heating a solution to high temperature to obtain much larger calcium phosphate particles. There is nothing in Roeder, or otherwise identified by the Examiner, that would lead one skilled in the art to modify the process of Roeder to arrive at the process of claims 10 or 11 amended.

The Examiner further cites the brief references in Roeder to the use of smaller particles of calcium phosphate in the matrices (Paragraph [0035]) or the dry mixing of calcium and phosphate containing compounds having smaller particle size (Paragraph [0047]). In these processes, the calcium phosphate particles are already formed and are either added to a matrix or dry mixed to form calcium phosphate cement material. These processes are entirely different from the processes of claim 10 and 11 as amended, and they cannot be modified in a manner to arrive at the claimed process.

Accordingly, for at least the reasons set forth above, claims 10-15 and 19-22 are not obvious in view of Roeder, and this grounds for rejection should be withdrawn.

Rejection of Claims 14 and 21 Under 35 U.S.C. Section 103(a) Based on Roeder and Kumta

Claims 14 and 21 stand rejected under 35 U.S.C. § 103(a) as being unpatentable as obvious over Roeder in view of Kumta et al., U.S. Patent No. 7,247,288 ("Kumta"). Claims 14 and 21 depend from claims 10 and 11 respectively and recite that the phosphate compound used in the process is an ammonium phosphate. The Examiner states that it would be obvious to use ammonium phosphate as taught by Kumta in the process of Roeder.

As discussed above, Roeder describes a process in which a solution containing calcium and phosphate is heated to 200°C for a period of time to produce calcium phosphate precipitates having an average length of 19 μm (19,000 nm) or more and a width of 2.3 μm (2,300 nm) or more. Simply replacing the form of the initial phosphate used in the process of Roeder does not address the particle size obtained in the process. Indeed, Kumta describes larger agglomerates having a size of 2-5 mm. Neither Roeder not Kumta describe an aqueous dispersion having calcium phosphate platelets wherein at least 80% of the platelets are between 250-600 nm in length.

Moreover, one skilled in the art would not combine Roeder and Kumta as suggested by the Examiner. The process of Roeder requires that the pH of the solution be maintained at 4, while Kumta's method utilizes reaction conditions with a very high pH of 11-12. Kumta explicitly teaches the necessity of including NaOH in the reaction solution to maintain a high pH during the initial reaction between the phosphate and the calcium salt. Kumta discloses that dropping to below pH 9

results in calcium-deficient hydroxyapatite, which is inferior and unstable at elevated temperatures (Kumta, col. 15, lines 15 to col. 16, line 36). The high pH method was deliberately selected by Kumta to prepare hydroxyapatite for use in gene delivery (Kumta, Example 2, col. 18, lines 16-17).

There is no reason given that one skilled in the art would use the ammonium phosphate of Kumta in the low pH, high temperature process of Roeder with a reasonable expectation of success. Moreover, there is nothing in Kumta that suggests modifying the process of Roeder in a manner that would produce the aqueous dispersion recited in claims 14 and 21. Accordingly, for at least the reasons set forth above, Applicant submits that claims 14 and 21 are patentable over Roeder and Kumta and requests that the rejections of these claims be withdrawn.

Double Patenting Rejection

Claims 1-5, 9-15, 17 and 19-22 stand rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-6 of U.S. Patent No. 7,807,724 ("the '724 patent"). Claims 1-6 of the '724 patent recite a process for making a colloidal dispersion of calcium phosphate by combining solutions containing calcium and phosphate. In the processes of the '724 patent, the colloidal dispersion is formed by adding at least one polymer which complexes calcium to the solution before the solution are heated to form the calcium phosphate platelets. It would not be obvious the one skilled in the art to omit the complexing polymer from the solution and arrive at the aqueous dispersions or the process recited in claims 1-5, 9-15, 17 and 19-22. There is nothing in the cited reference to have a reasonable expectation of success without the complexing polymer in the mixture. Accordingly, 1-5, 9-15, 17 and 19-22 are not obvious in view of the '724 patent, and the rejection on double patenting grounds should be withdrawn.

In view of the amendments to the claims and the foregoing remarks, the pending claims are believed to be allowable over the prior art of record. Accordingly, it is respectfully requested that this application be allowed and a Notice of Allowance be issued. If the Examiner believes that a telephone conference with Applicants' attorney would be advantageous to the disposition of this case, and in particular if a terminal disclaimer is required for allowance, the Examiner is cordially requested to telephone the undersigned. If the Examiner has any questions in connection with this

paper, or otherwise if it would facilitate the examination of this application, please call the undersigned at the telephone number below.

Because the reasons above are sufficient to traverse the rejection, Applicants have not explored, nor do they now present, other possible reasons for traversing such rejections. Nonetheless, Applicants expressly reserve the right to do so, if appropriate, in response to any future Office Action.

A Petition for a Three Month Extension of time and the associated fee has been filed herewith. No additional fee is believed to be required. In the event the Commissioner of Patents and Trademarks deems additional fees to be due in connection with this application, Applicant's attorney hereby authorizes that such fee be charged to Deposit Account No. 50-3569.

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